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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,548	02/07/2001	David M. Lubman	UM-06102	5017
23535	7590	06/29/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			MARSCHER, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/778,548

Applicant(s)

LUBMAN ET AL.

Examiner

Ardin Marschel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35,38-51,53-67,69-77 and 79-91 is/are pending in the application.
- 4a) Of the above claim(s) 1-32,34,40-44,50,55-58,71 and 83-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,35,38,39,45,46,49,51,53,54,59-67,69,70,72-77,79-82,88 and 89 is/are rejected.
- 7) ☒ Claim(s) 38,47,48,51,67,73,90,&91 is/are objected to.
- 8) ☒ Claim(s) 1-35,38-51,53-67,69-77 and 79-91 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/22/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Attachment for PTO-948</u> . |

DETAILED ACTION

Applicants' arguments, filed 4/8/04, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

DRAWING OBJECTIONS

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is enclosed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

NOT FURTHER LIMITING CLAIMS

Claims 38, 51, 67, and 73 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The independent claims under examination have been amended to be limited to requiring isoelectric focusing as a first separating apparatus. Claims 38, 51, 67, and 73

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are not further limiting due to citing a broader type of first separating apparatus directed to being a liquid phase separating apparatus.

PRIOR ART

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33, 35, 38, 45, 46, 49, 51, 54, 59-67, 69, 72-77, 79-81, 88, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jindal et al. (P/N 6,358,692); taken in view of Naveh et al. (P/N 5,451,662).

Jindal et al. is reiterated as applied to the basic instant invention as set forth in the previous office action, mailed 1/5/04. Jindal et al., however, does not specifically cite isoelectric focusing as a first separating step therein. Jindal et al. was previously described and pointed to as directing multiple or tandem column chromatography techniques in column 14, lines 40-52. The first sentence of this citation particularly suggests and motivates the practice of any column in said method as desired for separating molecules in the tandem arrangement of Jindal et al. In the BACKGROUND

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section of Jindal et al. in columns 1-2 further discussion is present wherein the screening of complex library mixtures of, optionally random sequence) proteins or peptides is described as requiring multiple passes utilizing different chromatography columns (column 1, lines 25-31) and that a major hurdle is the chemical characterization of ligands in such screening to identify ligands, as in column 2, lines 47-49. Thus amply motivation is present in Jindal et al. to utilize any added chemical characterization method for protein purification or screening from complex mixtures.

Naveh et al. summarizes in the abstract the usage of isoelectric point determination via chromatography to separate even closely related impurities in crude proteins. In column 1, lines 16-21, the desire to separate closely related proteins such as expected to be present in large libraries as set forth in Jindal et al. is discussed. pH separation via charge or isoelectric focusing chromatography is summarized in Naveh et al. in column 2, line 42, through column 5, line 29, wherein pH defined fractions are produced.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to add isoelectric focusing chromatography as in Naveh et al. to obtain the suggested and motivated added chemical characterization thereof within the tandem chromatograph of Jindal et al. to result in the practice of the instant invention. It is noted that the libraries utilized in the references is inclusive of a broad scope of types such as being obtained from host organisms, cell lysates, etc. as set forth in Jindal et al. in column 7, line 47, through column 8, line 44. Cell lysates as in

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instant claims 35 and 76 is cited in Jindal et al. specifically as a protein source in column 8, lines 25-29.

Claims 33, 35, 38, 39, 45, 46, 49, 51, 53, 54, 59-67, 69, 70, 72-77, 79-82, 88, and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jindal et al. (P/N 6,358,692); taken in view of Naveh et al. (P/N 5,451,662); taken further in view of Verentchikov et al. (P/N 6,534,764).

The combination of Jindal et al. in view of Naveh et al. has been summarized above, however, only cites generic mass spectroscopy practice. Such generic mass spectroscopy practice is reasonably suggestive and motivating to utilize prior art mass spectroscopy practices, especially if such practices are further motivated via improved performance thereof.

The instant claim embodiments rejected hereunder are those directed to the basic invention based on Jindal et al. in view of Naveh et al. but additionally requiring the specific mass spectroscopy of ESI or TOF.

Verentchikov et al. describes an improvement in mass spectroscopy regarding certain types therein directed to TOF methods and instruments as summarized in the abstract. Columns 1-5 of Verentchikov et al. summarize developments in mass spectrometry and indicate yet a further need for improvement thereof. In the SUMMARY OF THE INVENTION section in columns 5-7 of Verentchikov et al. improvements are summarized via mass spectrometry utilized therein including ESI ion sources in column 7, lines 5-10. In column 8, line 20, through column 15, line 67, detailed mass spectrometry for said improvements are detailed wherein a specific type

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of practice is orthogonal acceleration as specifically cited in column 9, lines 63-67, as a described mass spectroscopy practice. Generic samples are described in Verentchikov et al., however, peptide samples are clearly given a reasonable expectation of success in such a practice via being exemplified in column 17, lines 4-16, as practice in the instant invention.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to utilize ESI or TOF mass spectrometry motivated by the advantages cited in Verentchikov et al. within the combination of practices of Jindal et al. in view of Naveh et al. to result in the practice of the instant invention with a reasonable expectation of success.

Verentchikov et al. is applicable as a reference due to its priority document written basis in provisional priority document serial number 60/138,861.

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicate that a copy was not readily available, it is because the copy could not be readily obtained when the Office action was mailed. Should applicant desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge will not apply.

CLAIM OBJECTIONS

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Claims 47, 48, 90, and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

June 25, 2004

 6/25/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER